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**REMARKS/ARGUMENTS**

Claims 1-14 and 48 were pending. Claims 15-47 are canceled without prejudice or disclaimer. New claim 49 is added. Claims 1, 4, 7, 8 and 9 are amended herein. Claims 1-14 and 48-49 are presently pending.

**Change of Correspondence Address**

Applicants note that the instant Office Action was mailed to Foley and Lardner I.I.P. Applicants further note that a Power of Attorney and Change of Correspondence Address (attached) was filed in this application on 8/21/06 and is listed on PAIR as being entered in the case. According to the POA and Change of Correspondence, the attorney of record is now Faegre & Benson LLP and correspondence is to be sent to the address associated with Customer Number 35657. Applicants respectfully request that the Office take note of the Power of Attorney and Change of Correspondence Address and that all future correspondence be addressed to Faegre & Benson LLP, Patent Docketing, 2200 Wells Fargo Center, 90 South 7<sup>th</sup> Street, Minneapolis, MN 55402-3901.

**Claim Amendments**

Claim 1 is amended to replace "drug" with "chemotherapeutic agent" and to recite the limitation of performing enzyme pretargeting with bispecific antibodies or fragments, with one arm binding to a target site antigen and a second arm binding to a low molecular weight hapten conjugated to the enzyme. The amendment is supported by original claims 4 and 7 and in the published Specification (No. 20020114808) at least at Paragraph Nos. [0002], [0006], [0007], [0019], [0040]-[0046] and Examples 3-7.

Claim 4 is amended to recite the method of claim 1, wherein the bispecific antibody or fragment comprises murine, chimeric or humanized antibodies or fragments. The amendment is supported in the published Specification at least at Paragraph [0019] and Examples 3-7.

Claim 6 is amended according to the Action's suggestion. Support may be found in the published Specification at least at Paragraphs [0044], [0076] and [0078].

Claim 7 is amended to recite the first arm of the bispecific antibody of claim 1 comprising a humanized MIN-14 or anti-CFA antibody or fragment and the second arm

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comprising an anti-DTPA or 734 antibody or fragment. Applicants note that hMIN-14 is a species of anti-CEA antibody and 734 is a species of anti-DTPA antibody, as discussed in Paragraph [0070] of the published Specification.

Claims 8 and 9 are amended to depend from claim 1, since amended claim 1 contains the limitation of original claim 7.

Claim 11 is amended to conform with amended claim 1.

New claim 49 recites the antibody fragment comprising an Fab, Fab', F(ab)<sub>2</sub>, F(ab')<sub>2</sub> or scFv fragment. The amendment is supported in the published Specification at least at Paragraph [0019].

#### **Claim Objections**

Claim 6 is amended as suggested by the Action to address the objection.

#### **Claim Rejections -- 35 U.S.C. § 112**

Claims 1-3, 6-14 and 48 are rejected under 35 U.S.C. §112, first paragraph for failure to comply with the written description requirement. The Action asserts that the Specification provides written description support only for cytotoxic chemotherapeutic agents. Although Applicants respectfully traverse the assertion, in the interests of advancing prosecution claim 1 is amended to replace "drugs" with "chemotherapeutic agents." Since the Action at pg. 4, 1<sup>st</sup> paragraph and pg. 6, 3<sup>rd</sup> paragraph acknowledges written description support for the sub-genus of "chemotherapeutic agents," Applicants submit that the amended claims satisfy the written description requirement of 35 U.S.C. § 112, 1<sup>st</sup> paragraph. Reconsideration and withdrawal of the rejection are respectfully requested.

#### **Claim Rejections -- 35 U.S.C. § 102**

Claims 1-4, 11 and 48 are rejected under 35 U.S.C. 102 as anticipated by Hansen et al. (WO 91/08770). The Action asserts that Hansen, "teaches that the enzyme is pretargeted to a target cell using an antibody-enzyme conjugate (page 5, lines 14-15." [Action at pg. 7, 1<sup>st</sup> paragraph] Applicants note that the present claims specifically recite pretargeting using bispecific antibodies, with one arm binding to a target site antigen and a second arm binding to a low-molecular weight hapten that is conjugated to the enzyme. As this element is not disclosed

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by Hanson, the amended claim is not anticipated by the Hanson reference. Reconsideration and withdrawal of the rejection are requested.

#### **Claim Rejections – 35 U.S.C. § 103**

Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen et al in view of Griffiths et al. (WO 96,40245). Neither Griffiths nor Hansen is asserted by the Action to disclose the element of pretargeting using bispecific antibodies, with one arm binding to a target site antigen and a second arm binding to a low-molecular weight hapten that is conjugated to the enzyme, as recited in amended claim 1. Further, original claim 7 was not rejected by the Action under either 35 U.S.C. §§ 102 or 103 over the prior art. As amended claim 1 now contains the limitations of original claim 7, Applicants assert that all claims are now allowable over the cited prior art.

#### **Double Patenting**

Claims 1, 7 and 11 are rejected on the ground of nonstatutory obviousness-type double patenting over claim 1 of U.S. Patent No. 7,074,405.

Claims 1, 4-5, 7 and 11 are rejected on the ground of nonstatutory obviousness-type double patenting over claim 1 and 4-5 of U.S. Patent No. 7,074,405.

Applicants respectfully traverse the rejection and assert that the “hapten” of the instant claims is not obvious over the “carrier” of the ‘405 patent. In fact, the first paragraph of the Detailed Description of the ‘405 patent states that, “The targetable conjugate comprises a carrier portion which comprises or bears at least one epitope recognized by at least one arm of the bi-specific antibody or antibody fragment. In a preferred embodiment, the epitope is a hapten.” Thus, the ‘405 patent discloses that the instant claimed hapten is only one component of the “carrier” claimed in the ‘405 patent and in fact teaches away from the instant claimed invention, by leading the skilled artisan to consider the present claimed “hapten” to be only one component of a carrier that may be linked to an enzyme.

However, in the interests of advancing the prosecution, Applicants will submit a terminal disclaimer over the ‘405 patent once otherwise allowable subject matter is found.

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**Conclusion**

For the reasons stated above, Applicants submit that the amended claims are in condition for allowance and request withdrawal of the rejections.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Richard A. Nakashima', is written over a horizontal line.

Richard A. Nakashima  
Reg. No. 42,023

Dated: November 27, 2006